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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,654	03/29/2001	Kenichi Hosoya	10939/2012	6149

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 05/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/821,654

Applicant(s)

HOSOYA ET AL.

Examiner

Daniel M Sullivan

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-14.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.

Continuation of 5. does NOT place the application in condition for allowance because: Claims 1-14 were rejected under 35 U.S.C. §112, first paragraph, as lacking adequate support for the limitation, "wherein the cell is limited to a cell that does not comprise a heterologous antibiotic resistance gene" in the originally filed disclosure. In response, Applicant argues, "the amendment simply makes explicit what is inherent in the specification" (page 6 of Paper No. 19, filed 16 May 2003). Applicant cites *Ex parte Parks*, 30 U.S.P.Q.2d 1234 (BPAI, 1993) wherein the Board reversed a rejection based on the addition of a negative limitation. Applicant asserts that, as in the *Parks* case, the present disclosure would cry out for explicit recitation of an antibiotic resistance gene if one were used. Applicant states, "Applicants clearly teach how to make the claimed cells; however, nowhere do they teach how to make a cell containing a heterologous antibiotic resistance gene" (Id at page 6).

These arguments have been fully considered but are not found persuasive. First of all, it should be pointed out that the heterologous antibiotic resistance gene is not limited to any particular type of antibiotic resistance gene (i.e., prokaryotic or eukaryotic). On pages 13 and 14 of the specification, Applicant describes introducing a gene encoding tsA58 into cells wherein the tsA58 gene is in a pBR322 plasmid. It is known in the art that pBR322 carries two heterologous antibiotic resistance genes (i.e., Amp^r and Tet^r). Applicant does not teach that said antibiotic resistance genes should be removed; therefore, the skilled artisan would assume that the heterologous antibiotic resistance genes were still in the plasmid when the construct was introduced into the cells, and would be present in the resultant cells. Central to the finding of the Board in the case of *Parks* was that "it cannot be said the originally-filed disclosure would not have conveyed to one having ordinary skill in the art the concept of effecting decomposition at an elevated temperature in the absence of a catalyst" (page 1237). In the instant case however, the limitation of a cell that does not contain a heterologous antibiotic resistance gene would clearly not have been conveyed by the teachings of the specification because it would appear to the skilled artisan that the cells do, in fact, contain a heterologous antibiotic resistance gene.

Furthermore, even if the claims had been limited to a cell that does not contain a eukaryotic cell antibiotic resistance gene, the limitation would not be inherent to the teachings of the specification. The use of antibiotic resistance genes is routine in the art and the skilled artisan would not understand based on the teachings of the specification that the claimed cells should not comprise such a gene. Applicant argues that the presence of an antibiotic resistance gene would affect the properties of Applicants' immortalized cells, making them unsuitable for subsequent transformations and selection using a neomycin resistance gene as a selective marker. This argument is not persuasive because the skilled artisan would know of many different antibiotic resistance genes that would not make the cells unsuitable for subsequent transformations and selection of transformed cells using neomycin resistance gene as a selective marker (i.e., bleomycin resistance gene, cytosine deaminase, dihydrofolate reductase, histidinol dehydrogenase, hygromycin-B-phosphotransferase, puromycin-N-acetyl transferase, thymidine kinase, xanthine-guanine phosphoribosyltransferase).

For these reasons, the instant disclosure would not have conveyed to one having ordinary skill in the art the concept of a cell that does not contain a heterologous antibiotic resistance gene. Therefore, the claims stand rejected..



JAMES KETTER
PRIMARY EXAMINER